In re application of:

Andrew A. YOUNG et al.

Appln. No.: 09/889,330

371 Filing Date: December 27, 2001

For: Novel Exendin Agonist Formulations

and Methods of Administration

Thereof

Group Art Unit: 1614

Examiner: To Be Assigned

Atty. Docket: 18528.127

Confirmation No.: 2741

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

The attention of the Examiner is invited to the documents listed on the attached Form PTO-1449. Copies of the listed documents are submitted herewith.

It is respectfully requested that the information above be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Applicants note that the article by Goke *et al.* was previously submitted with the Information Disclosure Statement filed August 20, 2002.

## **CERTIFICATION AND/OR FEE**

Because this Information Disclosure Statement is being submitted prior to issuance of the first action on the merits of the above-captioned application, no certification or fee is required.

Applicants certify that each of the documents listed on the attached Form PTO-1449 was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement and, therefore, no fee is required.

Respectfully submitted,

David R. Marsh (Reg. No. 41,408) Milan M. Vinnola (Reg. No. 45,979)

Date: October 20, 2003

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|           |     |   | <del></del>         |               | December 27, 2001                 |             | 1614        |       |             |          |
|-----------|-----|---|---------------------|---------------|-----------------------------------|-------------|-------------|-------|-------------|----------|
| EXAMINER  | ·   | I poor  |                     | U.S. PA       | TENT DOCUMENTS                    | <del></del> |             |       |             |          |
| INITIAL   |     | DOCUMENT<br>NUMBER  | PUBLICATION<br>DATE | NAME          |                                   |             |             | SUB-  |             |          |
|           | AA1 | 6,506,724 B1  | 1/2003              | Hiles et al   | 1.                                |             | CLASS       | CLASS | FILING DATE | <u> </u> |
|           | AB1 | US 2003/<br>0087821 A1  | 5/2003              | Beeley et a   |                                   |             | <del></del> |       |             |          |
| EXAMINER  |     |   | •                   | FOREIGN       | PATENT DOCUMENTS                  |             |             |       |             |          |
| INITIAL   |     | DOCUMENT<br>NUMBER  | DATE                | COUNTRY       |                                   |             |             | SUB-  |             |          |
|           |     |   |                     |               |                                   |             | CLASS       | CLASS | TRANSLATION | Yes      |
|           |     |   | OTHER (             | Including Aut | hor, Title, Date, Pertinent Pages |             |             |       |             | No       |
|           | AD1 | Securities Exchange Act of 1934, March 15, 2002, pages 1-8.  Baggio et al., "Sustained Expression of Exendin-4 Does Not Perturb Glucose Homeostasis, β-Cell Mass, or Food Intake in Metallothionein-Preproexendin Transgenic Mice," J. Biol. Chem. 275(44):34471-7 (2000).  |                     |               |                                   |             |             |       |             |          |
|           | AF1 | Edwards et al., "Exendin-4 Reduces Fasting and Postprandial Glucose and Decreases Energy Intake in Healthy Volunteers," Am. J. Physiol. Endocrinol. Metab. 281:E155-61 (2001).  Egan et al., "The Insulinotropic Effect of Acute Exendin-4 Administered to Humans: Comparison of Nondiabetic State to Type 2 Diabetes," J. Clin. Endocrinol. & Metab. 87(3):1282-90 (2002). |                     |               |                                   |             |             |       |             |          |
|           | AH1 | Goke et al., "Exendin-4 Is a High Potency Agonist and Truncated Exendin-(9-39)-amide an Antagonist at the Glucagon-like Peptide 1-(7-36)-amide Receptor of Insulin-secreting β-Cells," J. Biol. Chem. 268(26):19650-55 (1993) (previously submitted on August 20, 2002).  |                     |               |                                   |             |             |       |             |          |
|           | AI1 | International Search Report, International Application No. PCT/US03/16699 (August 2003)   |                     |               |                                   |             |             |       |             |          |
| AMINER    | AJ1 | Tourrel <i>et al.</i> , "Persistent Improvement of Type 2 Diabetes in the Goto-Kakizaki Rat Model by Expansion of the β-Cell Mass During the Prediabetic Period with Glucagon-Like Peptide-1 or Exendin-4," <i>Diabetes</i> 51:1443-52 (2002).  |                     |               |                                   |             |             |       |             |          |
| TIVILINEK |     |   |                     |               |                                   |             | -           |       | (200)       | ٠)٠      |

EXAMINER DATE CONSIDERED

**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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